ASX Announcement

CLEO Appoints CRO to Manage U.S. Ovarian Cancer Clinical Trials

Highlights

- **CLEO has appointed U.S.-based Lindus Health to manage U.S. clinical trials for its revolutionary ovarian cancer blood test**
- **Lindus Health is a leader in clinical trial management for the med-tech sector, with a strong record of timely and successful trial execution**
- **CLEO's U.S. study will prospectively recruit up to 500 patients commencing next month and will verify the performance of CLEO's pre-surgical ovarian cancer test for FDA regulatory approval.**

MELBOURNE, AUSTRALIA, 11 April 2024: Ovarian cancer diagnostics company, Cleo Diagnostics Limited (ASX:**COV**) (**CLEO**, or the **Company**) is pleased to announce the appointment of international Contract Research Organization (**CRO**), Lindus Health, as a key partner for its U.S. clinical trials program.

U.S. Ovarian Cancer Clinical Trials

As a part of CLEO's U.S. market access program, the Company will partner with U.S.-based CRO, Lindus Health, appointing it to manage the successful execution of its ovarian cancer U.S. clinical trials. Lindus Health was chosen following a robust process to identify a partner with the proven experience, technology and high standards capable of delivering on CLEO's objectives.

Lindus Health specialises in collaborating with med-tech companies to conduct clinical trials worldwide, leveraging their innovative patient recruitment and trial management technology platform to deliver efficient and timely outcomes.

Comprehensive U.S. patient data is essential for a successful regulatory application through the Food and Drug Administration (**FDA**). CLEO will leverage Lindus Health's expertise to execute a cost-effective and rapid clinical study that will support its subsequent FDA 510(k) application.

The study will benchmark CLEO's pre-surgical ovarian cancer triage test and provide the core data requirements for the FDA 510(k) application. Up to 500 U.S.-based patients will be recruited, with the trial scheduled over 10 months following ethic approvals and site engagement.

An Australian arm of the trial will also run concurrently and be managed directly by CLEO. This dual-arm strategy mitigates risk to the timelines due to patient recruitment, and will provide additional patient samples for kit verification following manufacture.

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The study data will be published in the mainstream medical literature as a part of CLEO's rigorous publication strategy.

Commenting on the partnership with Lindus Health, CLEO Chief Executive, Richard Allman, said:

"With the appointment of Lindus Health, our U.S. market access program is well underway to achieve our goal of obtaining regulatory approval for CLEO's initial pre-surgical market in the U.S. for our ovarian cancer blood test.

CLEO is appointing high calibre partners that we believe will help us deliver our important ovarian cancer detection technology to improve the health outcomes for women."

-ENDS-

This ASX announcement was authorised for release on behalf of the CLEO Diagnostics Ltd Board by:
Richard Allman, Chief Executive Officer.

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About Lindus Health

Lindus Health's mission is to accelerate reliable clinical trials for life science pioneers, so patients can benefit from ground-breaking new treatments sooner. Lindus Health does this by using software and EHR data to design better clinical trials, recruit participants and run a trial efficiently, from electronic data capture, to data management and consenting. Lindus operates in the US, UK and Europe helping companies run studies up to 2x faster than traditional CROs.

About Cleo Diagnostics Ltd ASX:COV

CLEO aims to bring to market a simple blood test for the accurate and early diagnosis of ovarian cancer based on the novel patented CXCL10 biomarker, which is produced early and at high levels by ovarian cancers but is largely absent in non-malignant disease. The test aims to distinguish benign from malignant growths in a standard format that will be readily compatible with existing equipment used by diagnostic laboratories worldwide.

The platform is backed by over 10 years of scientific Research & Development at the Hudson Institute of Medical Research, with two clinical studies conducted with over 500 patients. Pursuant to a licence agreement with the Hudson Institute of Medical Research, CLEO has a worldwide exclusive licence to commercialise the intellectual property which underpins its operations and the ovarian cancer tests.

The clinical unmet worldwide need is urgent. An accurate and early detection blood test could shift survivability for ovarian cancer significantly as seen with other cancers. CLEO is advancing the availability of its simple blood test, under a modular execution strategy which is designed to eventually address all ovarian cancer detection markets with specific tests including surgical triage, recurrence, high risk, and early-stage screening.